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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,715	09/18/2003	Dimitrios Manoussakis	P-5808	4404
26253 7590 04/29/2010 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company 1 Becton Drive MC 110 Franklin Lakes, NJ 07417-1880				
EXAMINER				
WRIGHT, PATRICIA KATHRYN				
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1797				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/664,715

**Applicant(s)**

MANOUSSAKIS ET AL.

**Examiner**

P. Kathryn Wright

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-18, 20-24, 26-28, 30-86 and 114 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 33-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 16-18, 20-24, 26-28, 30-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed February 10, 2010 in which claim 16 was amended. The amendments have been thoroughly reviewed and entered. Claims 1-13 and 33-86 remain withdrawn. Claims 14, 16-18, 20-24, 26-28, and 30-32 are under prosecution.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 14, 16-18, 20-24, 26-28 and 30-32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hugh Conway (EP 1 107 002 A2), published June 13, 2001.

Conway teaches a container (tube 14) having an upper end 13, a closed lower end 14, and a sidewall 15 between the upper and lower ends 13, 14 having inner and outer walls 15a, 15b (see paragraphs [0022]). The tube includes a pierceable closure (stopper 18) therein.

Conway teaches a thixotropic gel 24 completely contained in deformable container or flexible bag 22. The bag 22 may be formed of materials which sufficient tackiness to promote adherence of the bag to the inner surface 15a of the tube to create first 22b and second 22a continuous regions seen in Figs. 1-3. The first region of the bag and gel is located at or adjacent the lower end 14a and the second region 22a extending upward from a portion of the first region 22b, wherein the first region comprises an imaginary upper boundary at which the first region exhibits 360° circumferential contact with the inner wall 14a, and wherein the first region comprises at least about 80 vol.% of the thixotropic gel. That is, as shown in the Figs. 1 and 2, the gel 24 substantially fills the first portion 22b of the bag 24 with only remaining second portion 22a being substantially absent of gel (see paragraph [0028]). Thus, it can be reasonably assumed that the first region of the gel comprises *at least about* 80 vol.% of the thixotropic gel.

Conway does not specifically disclose the gel in contact with a portion of the inner wall of the container. However, the use of thixotropic gel materials as a direct barrier for moving into an area adjacent the two phases of the sample being separated in order to maintain the components separated for subsequent examination of the individual components is well known in the art (see paragraphs [0002]-[0005] of Conway). The thixotropic gels used in separating blood components are typically chemically inert to most analytes present in blood samples. Thus, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to eliminate the flexible bag from the device of Conway since the use of such bags increases the manufacturing cost and complexity of the device.

As to claim 16, it appears the imaginary upper boundary of Conway exhibits a best fit plane within 10 degrees of a plane perpendicular to the longitudinal axis of the tube, see Figs. 2-3.

Regarding claims 17-18, Conway is silent to the distance between the first and second regions being between 8 to 21 mm, however, it the claimed distance would have been obvious to one of ordinary skill in the art through routine experimentation in an effort to optimize the operational parameters of the device.

As to claims 20-24, it is reasonable to assume the first region 22b of Conway comprises about 80 to 95 vol. % of the gel (claim 20), the interior surface of the thixotropic gel at the intersection of the first and second regions exhibits a radius of curvature between about 4 and about 8 mm (claim 21), wherein a best-fit plane to the exposed surface of the first region facing the interior of the container exhibits an angle of 25 ° or less with a plane substantially perpendicular to the longitudinal axis of the

container (claim 22), the exposed surface of the second region facing the interior of the container defines a best-fit plane exhibiting a 45 to 90° angle with a plane substantially perpendicular to the longitudinal axis of the container (claim 23), the best-fit plane to the exposed surface of the first region facing the interior of the container exhibits an angle of 90 to 140° with the best-fit plane to the surface of the second region facing the interior of the container (claim 24), wherein along a plane perpendicular to the longitudinal axis of the container located halfway between the average height of the exposed surface of the first region and the uppermost point of the second region (see Figs. 1-3).

As to claims 26-27, the second region 22a of Conway exhibits 80 to 140° circumferential contact with the inner surface, wherein the entirety of the second region exhibits less than 180° circumferential contact with the inner wall 15a and, wherein the entirety of the second region 22a exhibits less than 120° circumferential contact with the inner wall 15a, see in particular Figs. 1 and 2 of Conway.

### ***Response to Arguments***

6. Applicant's arguments filed February 10, 2010 have been fully considered but they are not persuasive. In response to the previous rejection of claims 14, 16-18, 20-24, 26-28 and 30-32 under 35 U.S.C. 103(a) as being unpatentable over Hugh Conway (EP 1 107 002 A2), applicant argues that Conway teaches away from the use of a thixotropic gel in direct contact with a blood sample or the separated components. Applicant also states that if the proposed modification would render the prior art invention unsatisfactory for its intended propose, then there is no suggestion or motivation to make the proposed modification (see MPEP 2143.01 (V)).

The examiner respectfully disagrees that Conway teaches away from the use of a thixotropic gel in direct contact with container and blood sample. In addition, the examiner respectfully disagrees that the proposed modification (i.e., elimination of the bag from the Conway device) would render the device inoperable for its intended purpose. The intended purpose of Conway is an assembly for separating a fluid sample into a higher specific gravity phase and a lower specific gravity phases using a flowable separation medium for moving adjacent the two phases of the sample being separated under centrifugal force in order to maintain separation of the heavier and lighter factions of fluid sample. The absence of a bag containing the thixotropic gel material would not prevent the gel from flowing and establishing a physical separation between the separated fluid phases because the practice of such placing thixotropic gels in direct contact with the separated blood components for providing a physical separation between the separated fluid phases is widely known in the art (see paragraphs [0002]-[0004] of Conway). See also paragraph [0002] of applicant's specification. Paragraph [0004] in Conway that states "[t]he most widely used device includes thixotropic gel material such as polyester or silicone gels. The present gel serum separation tubes require special manufacturing equipment to prepare the gel and to fill the tubes. Moreover, the shelf-life of the product is limited in that over time unbound resin may be released from the gel mass. This resin may have a specific gravity that is less than or equal to the separated serum and may float in the serum and may clog the measuring instruments such as the instrument probes used during the clinical examination of the sample collected in the tube..." (Emphasis added.) While the Conway reference stresses the use of a bag to prevent clogging and "possible" chemical interaction with

the blood sample, it does not teach away from the direct use of thixotropic gel for establishing a physical separation between the separated fluid phases. The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. See *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) and *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) in which the court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed." See also MPEP § 2131.05 and § 2145, subsection X.D.

The Examiner maintains that the thixotropic gels used in separating blood components are considered chemically inert to most analytes present in blood samples. Thus, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to eliminate the flexible bag from the device of Conway since the use of such bags increases the manufacturing cost and complexity of the device. In addition, it is worth noting that applicant cites the polyester-based separator gels in US Patent Nos. 4,101,422 and 4,148,764 both to Lamont, as known in the art and capable of being used in applicant's own invention. See paragraph [0033] of applicant's instant



specification. The separator gel in used in the Lamont references is a polyester-based thixotropic gel in direct contact with the blood sample. Conway teaches the most widely used device includes thixotropic gel material such as polyester or silicone gels (see paragraph [0004]). Lamont teaches that thixotropic gel material made of polyester-based compositions are not affected by contact with the blood and they do not alter the blood components. Such gels are known and accepted in the prior art as inert. See the summary of the invention section of both Lamont references and paragraph [0004] of Applicant's own invention. Thus, if the polyester-based separator gels used in the instant invention do not clog the measuring instruments and are chemically inert to the blood components, it is reasonable to assume the polyester-based thixotropic gels disclosed in Conway at paragraph [0004] also would not clog the measuring instruments and are chemically inert to the blood components when placed in direct contact with the blood sample.

Applicant argues that Conway fails to specifically disclose at least the claimed feature of the first region comprising at least about 80 vol. % of the gel. Applicant further argues that since Conway does not indicate the drawings are to scale, thus, the proportions of features in the drawing are of little value. Applicant also recognizes that paragraph [0028] of Conway discloses that the gel 24 substantially fills the first portion 22b (i.e., first region), but Applicant asserts that one cannot reasonably conclude as to what the term "substantially" means in relation to vol. % of gel.

While Examiner agrees that Conway disclosure did not indicate that the drawings were to scale, it is well established that the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of

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ordinary skill in the art. *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977). See MPEP 2125. The description of the Conway device at paragraph [00028] with respect to Figs. 1 and 2, states the gel 24 fills only a portion 22b (i.e., first region) of bag 22 with remaining portion 22a (second region), i.e., of the bag being collapsed and substantially absent of gel. The examiner asserts that this description of Figs. 1 and 2 in combination with drawings shown in Figures 1 and 2 would reasonably teach one of ordinary skill in the art that the first region (22b) comprises at least 80 vol. % of the thixotropic gel. In addition, the term "substantially" in the phrase "substantially absent" suggests for the most part or essentially absent of gel. Lastly, the limitation that the first region comprises at least 80 vol.% of the gel suggest that the first region can comprise all of the gel (i.e., 100 vol.%).

Thus, for the reasons delineated above, the claim remain rejected over the prior art.

### ***Conclusion***

7. No claims are allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. Kathryn Wright/  
Primary Examiner, Art Unit 1797